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[54] **DYNAMIC SPINAL SCREW-ROD CONNECTORS**

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[*] Notice: This patent issued on a continued prosecution application filed under 37 CFR 1.53(d), and is subject to the twenty year patent term provisions of 35 U.S.C. 154(a)(2).

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This patent is subject to a terminal disclaimer.

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[21] Appl. No.: **08/743,901**
[22] Filed: **Nov. 6, 1996**

Related U.S. Application Data

[63] Continuation of application No. 08/377,658, Jan. 25, 1995, Pat. No. 5,620,443.

[51] **Int. Cl.**⁷ **A61B 17/70**

[52] **U.S. Cl.** **606/61; 606/73**

[58] **Field of Search** 606/61, 60, 72, 606/73, 69, 70, 71, 57, 58; 623/17

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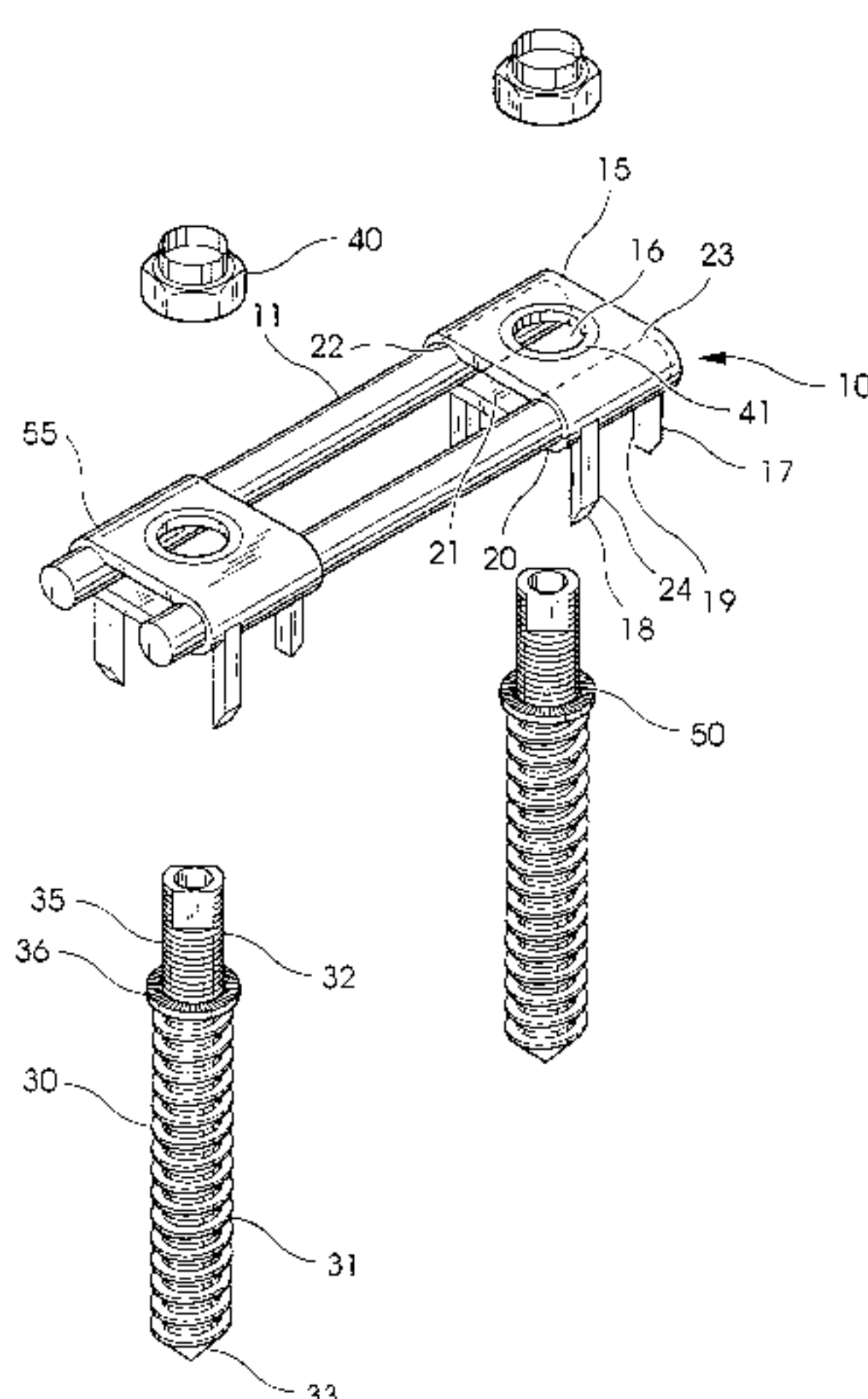
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[57] ABSTRACT

A transverse fixator assembly for spanning between a number of longitudinal members situated adjacent a patient's vertebrae and methods for fixation of the spine which allow variation of the distance between two or more vertebrae. The assembly includes a number of connectors configured to span the distance between and engage the longitudinal members. The connectors define a thru-hole for engaging a bone bolt which is engaged to a vertebra plus a number of spikes projecting from the connector. A locking mechanism is configured to prevent the bolt from rotating relative to the connector when the nut is being tightened. One or more of the connectors may be a dynamic connector which is slidably engaged to the longitudinal members to vary the distance between the vertebrae for compression or distraction.

21 Claims, 4 Drawing Sheets



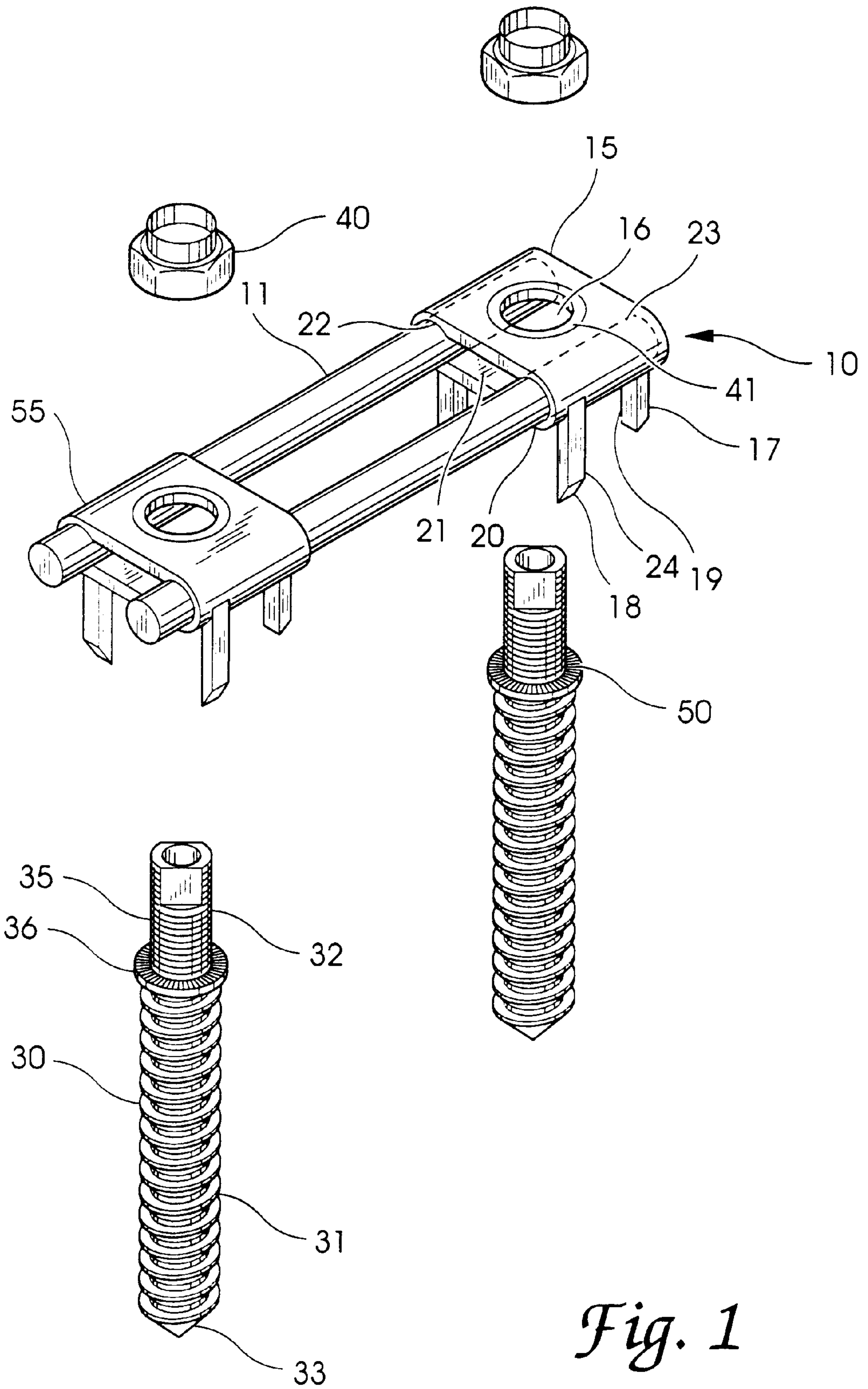


Fig. 1

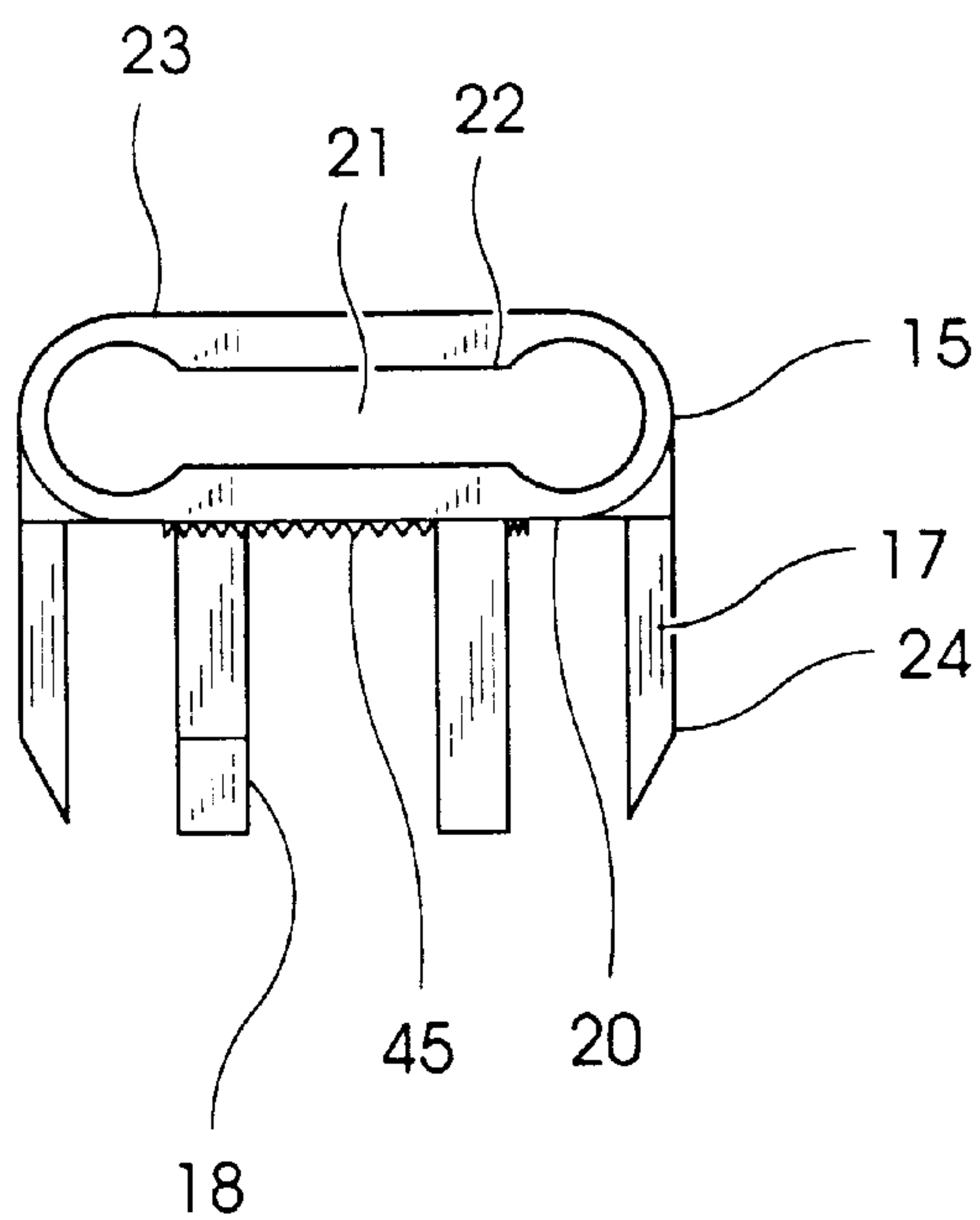


Fig. 2

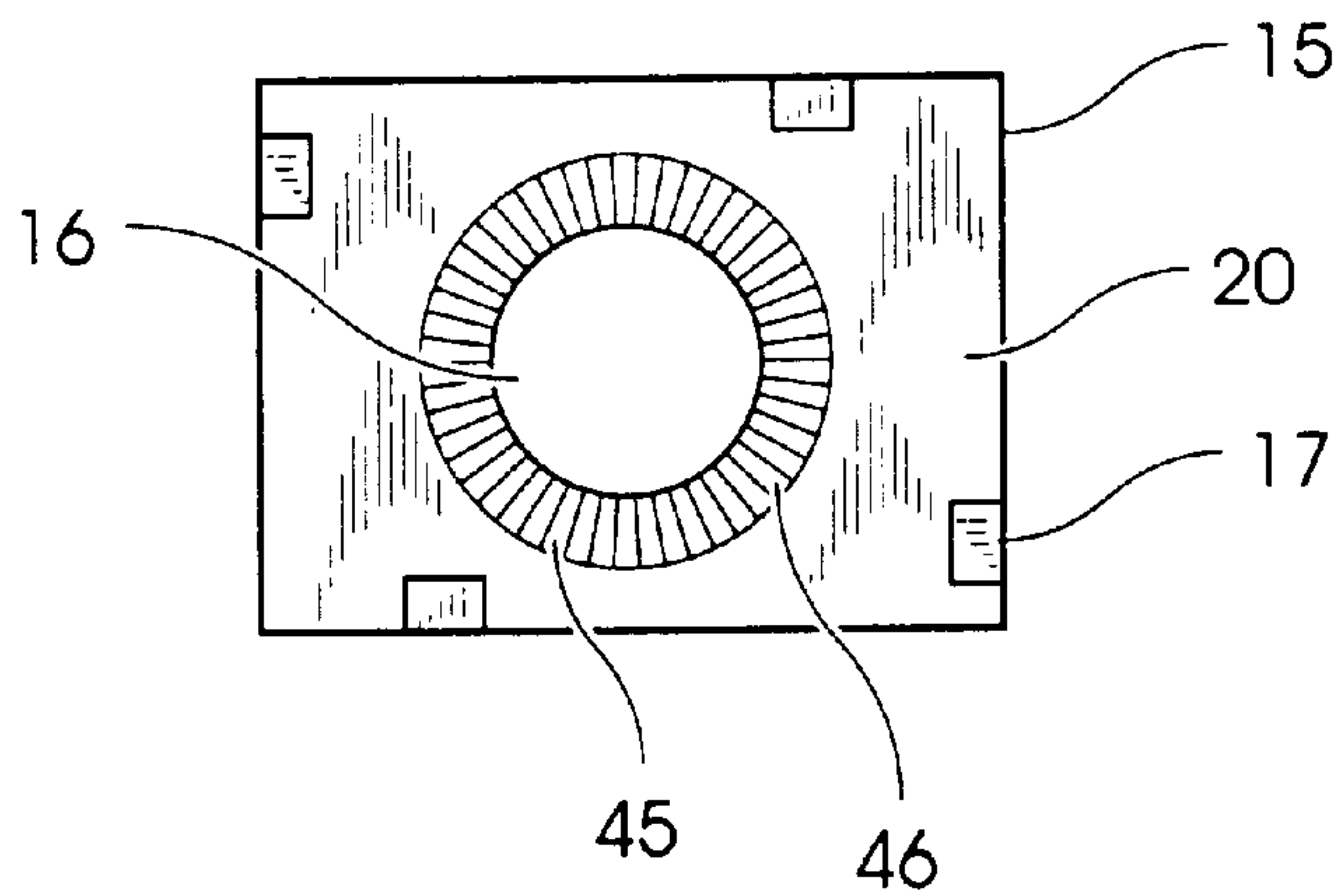


Fig. 5

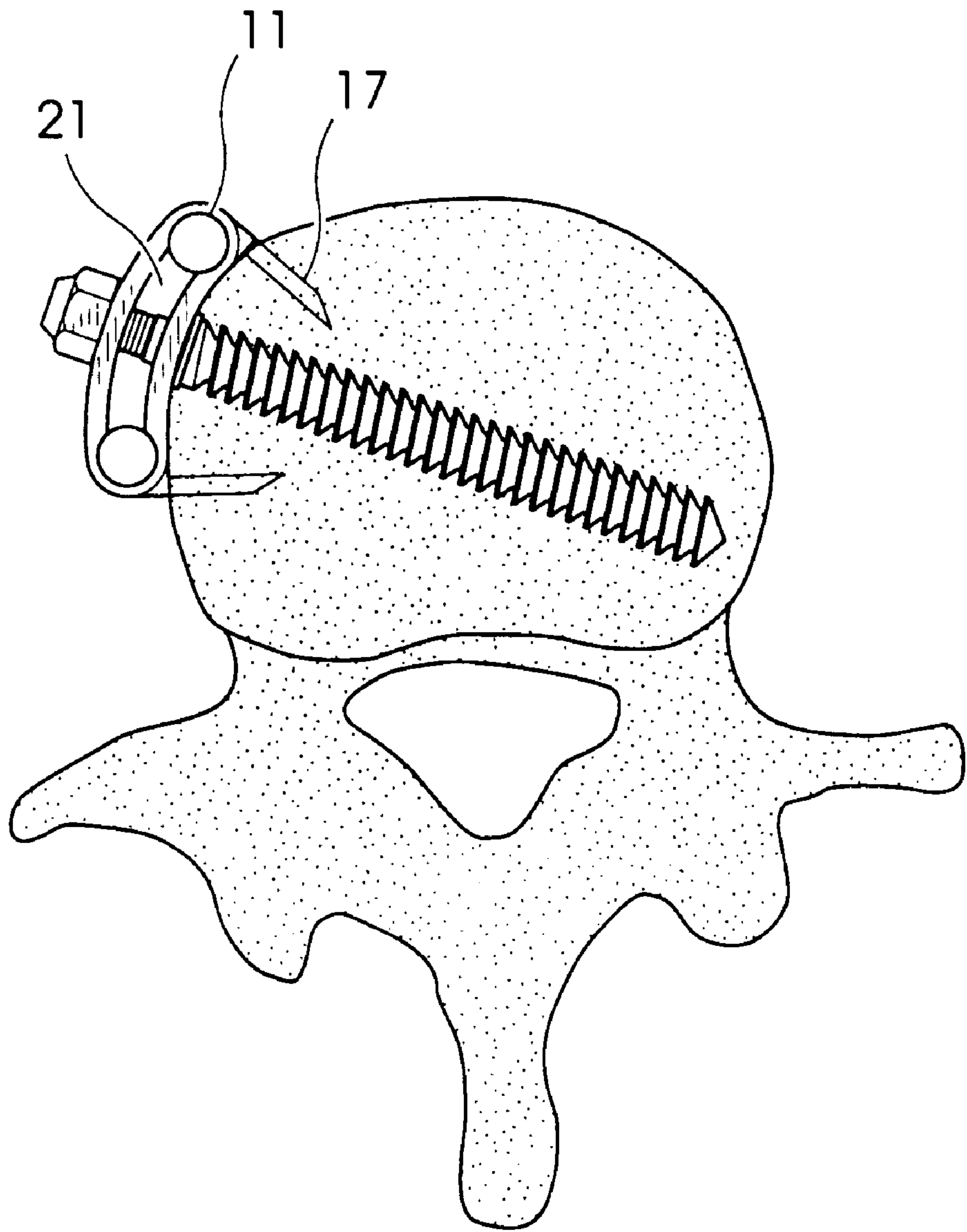


Fig. 3

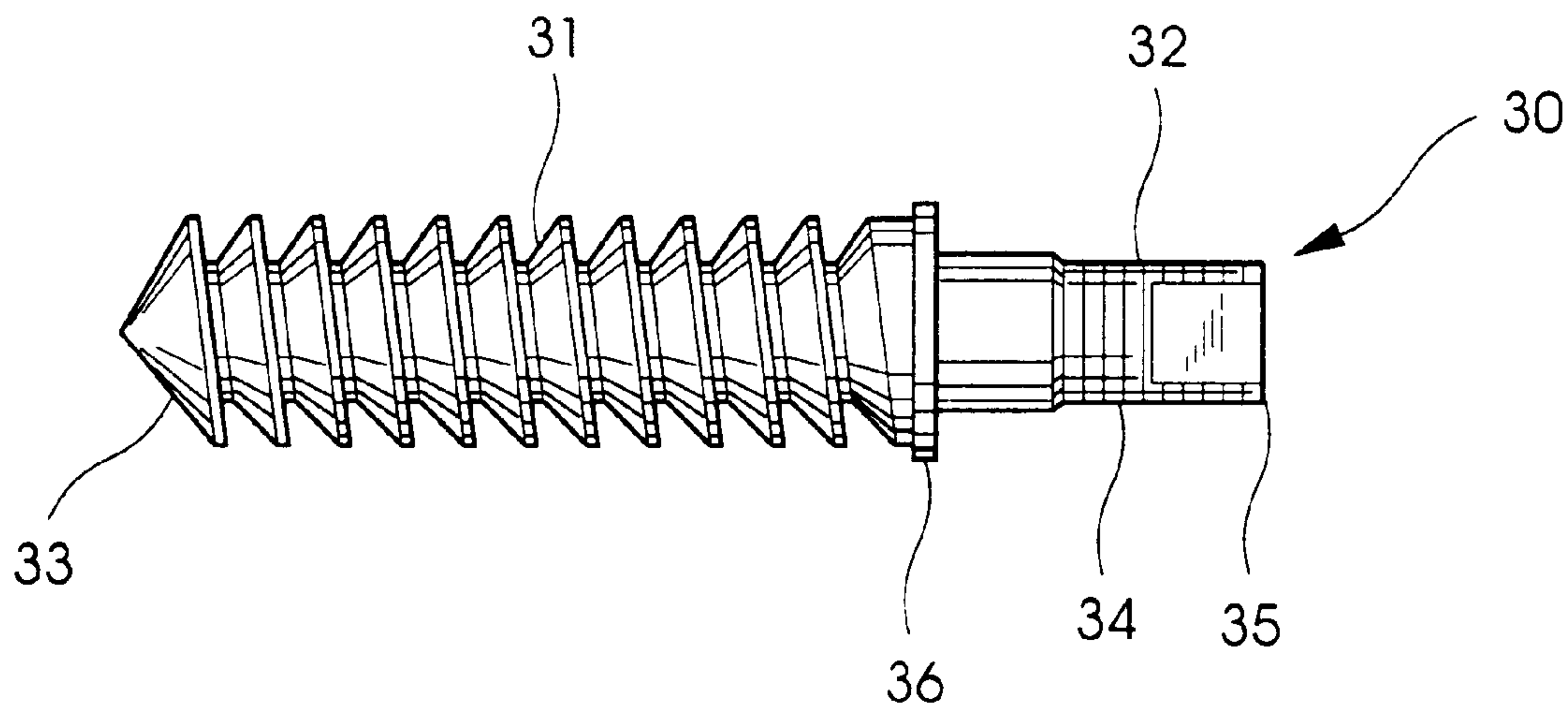


Fig. 4

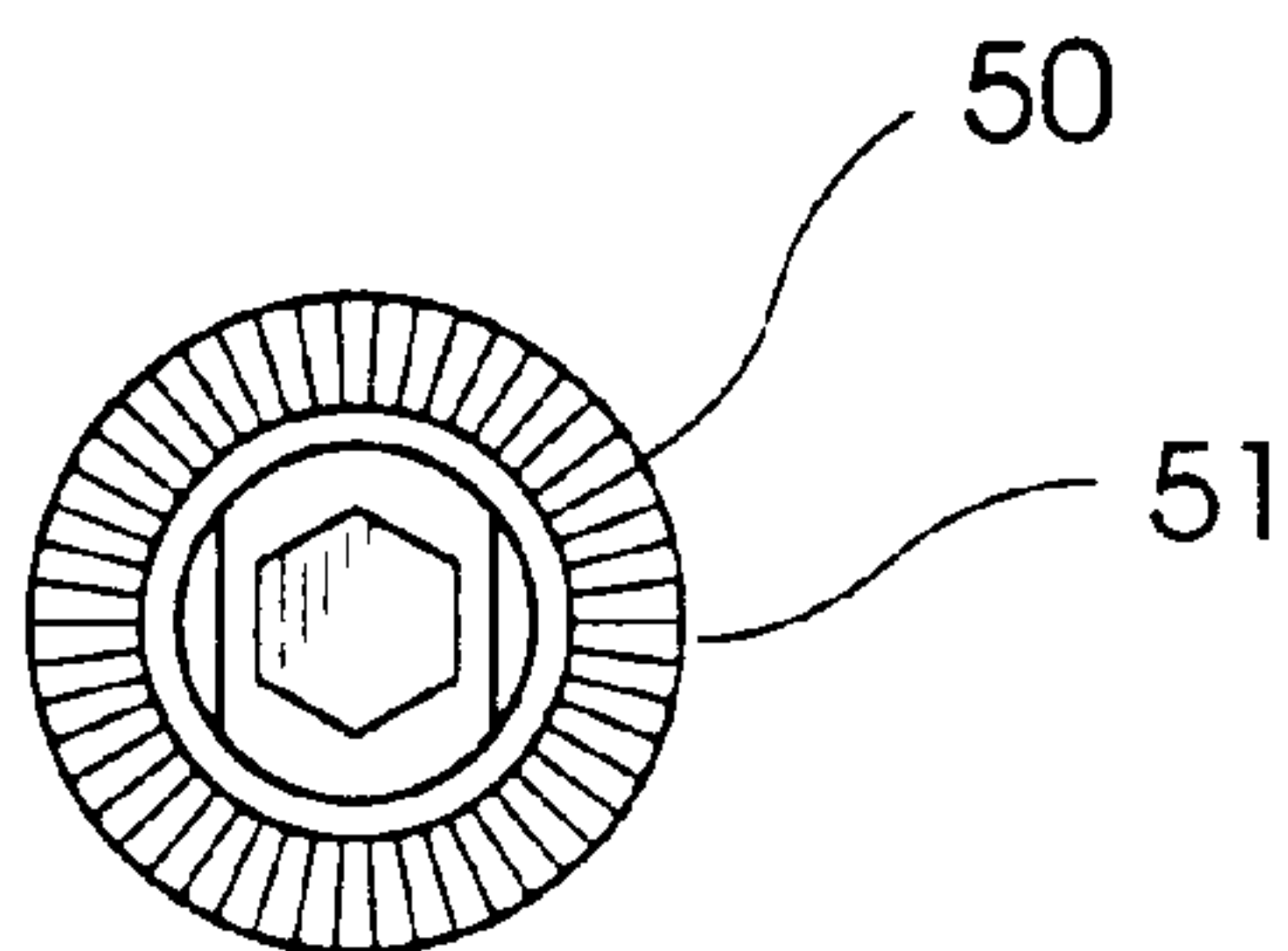


Fig. 6

DYNAMIC SPINAL SCREW-ROD CONNECTORS

This application is a continuation of Ser. No. 08/377,658 filed on Jan. 25, 1995 and issued as U.S. Pat. No. 5,620,443 on Apr. 15, 1997.

FIELD OF THE INVENTION

The present invention broadly concerns devices for use in spinal implant systems, particularly those using spinal rods contoured for connection at various locations along the length of the spinal column. More specifically, the invention concerns an apparatus for spanning between spinal rods to support vertebral fixation elements of the implant system which provide direct engagement to vertebrae of the spinal column. The invention is particularly useful with methods and devices for anterior fixation of the spine.

BACKGROUND OF THE INVENTION

Spinal fractures often occur at the thoracolumbar junction. Most of these fractures are burst injuries which are particularly dangerous because retropulsed bone fragments can cause spinal cord or caudal equina injuries. Posterior fixation has long been the primary approach for traumatic spinal injuries of this type.

The development of posterior internal fixation procedures for burst fractures was a substantial improvement over early approaches of bed rest and body casts. However, several disadvantages to these procedures were discovered. For example, this approach fails to reduce kyphosis or allow complete clearing of the spinal canal. Other complications include pseudoarthroses, late rod disengagement and inadequate reduction. Also, some posterior instrumentations require the fusion to extend at least two levels above and below the injury, particularly at the thoracolumbar junction. The posterior approach is also limited in the viability for use in burst fractures because in such fractures neural compression generally occurs from the anterior direction. Therefore, it is better to decompress and fuse the spine anteriorly. These difficulties have motivated attempts at anterior approaches. Various anterior and posterior spinal fixation devices and methods are discussed in Howard S. An, et al., (1992) *Spinal Instrumentation*, herein incorporated by reference.

There are several advantages to anterior internal fixation. An anterior approach allows complete clearance from the spinal canal of bone fragments and/or total resection of a tumor. It also permits fusion of a minimal number of motion segments. In spite of these advantages, the use of anterior approaches has been limited by the risk of complications and other disadvantages of current systems.

Several plate and screw systems have been designed for anterior instrumentation of the spinal column. The Syracuse I-Plate (Danek and Synthes) may use rigid or semi-rigid screws in combination with a plate. Distraction or compression of the bone graft is not possible with this system. The CASF Plate marketed by Acromed is designed to be used in a semi-rigid manner. This device, as well, does not permit compression or distraction of the bone graft and in addition cannot be used in a rigid construct. The Stafix Plating System marketed by Daruma of Taipei, Taiwan, is an anterior thoracolumbar plate designed to address similar indications. This plate incorporates slots and holes well as permitting quadrilateral placement of screws. The Anterior Thoracolumbar Plating System under development with Danek and Dr. Zdeblick is a slotted plate designed to attach to the anterior lateral aspect of the vertebral body. The plate

allows distraction and/or compression through the use of two screws and two bolts.

Several modular spinal instrumentation systems were developed for anterior instrumentation. The Kaneda device is a system which includes a rod coupler distant from the point of attachment to the vertebral bodies. Rods are inserted through holes in the spinal screw heads which are then attached to the superior and inferior vertebral bodies. Normally two screws are placed in each body, therefore two rods are required. These rods are threaded to allow compression and distraction and are connected to form a solid construct at the end of the procedure. The Texas Scottish Rite Hospital System is also a modular spinal system which can be used anteriorly for the management for burst fractures or tumors. This device can be configured much in the same way as the Kaneda device with two screws in the superior and inferior vertebral body, each connected by rods which are in turn connected together. The Dunn device is another anterior spinal fixation device for use in tumor or thoracolumbar burst fractures. This device, similar to Kaneda, involves vertebral body staples, screws positioned in the vertebral body, and two threaded rods connecting a superior and inferior vertebral body to form a rigid construct.

These systems have proved unsatisfactory. Many of these devices such as the Syracuse I-plate and the Casp plate do not allow distraction or compression of a bone graft in fusion cases. Such static systems cannot be used to correct certain disorders such as kyphosis. The systems that do allow distraction and/or compression are often too complicated and involve the use of multiple screws and bolts. The prominent bone screws and rods of some devices increase the danger of vascular injury. Hardware failures, such a screw pull-out, have led to complications, including pseudoarthrosis. Some systems are further limited because they cannot be used in a rigid construct.

It would therefore be desirable to have a low profile, streamlined system with a minimum of separately implanted components to reduce the amount of time required to implant the system, the risk of vascular injury and the problem of irritation to the surrounding soft tissue of the patient.

A need exists for devices for anterior fixation which reduce the risks of anterior fixation by providing a mechanism to prevent hardware failures, such as screw pull-out.

It is desirable to have a spinal fixation system that is readily adapted to provide lateral coupling between spinal rods and multiple stages or segments of the spinal column. Such a system should provide this segmental interconnection without interfering with vertebral areas available for bone grafting to achieve permanent fixation or immobilization of damaged vertebrae.

There is also a need for low profile, streamlined systems which allow variation of the distances between vertebrae, i.e., compression and distraction, without the need for complicated instrumentation and tools.

There is currently no system that addresses each of these features in a single apparatus. The present invention addresses these needs and provides other benefits not previously found in spinal fixation systems of the prior art.

SUMMARY OF THE INVENTION

In accordance with the invention, an apparatus is provided for spanning between a pair of longitudinal members situated adjacent a patient's vertebrae along the sagittal plane. The assembly includes a number of connectors which are engageable to the longitudinal members via clamping sur-

faces provided in a slot defined in the connector. Each of the connectors defines a thru-hole for engaging a bone bolt which in turn is engaged to a vertebral body. A fastener clamps the bone bolt to the connector. The assembly also includes a number of fixation spikes projecting from the connector which are configured to engage the vertebrae.

In a specific embodiment of the invention, there is provided a locking mechanism configured to prevent the bolt from rotating relative to the connector and the vertebra when the nut is being tightened. The locking mechanism may include radial splines on the lower surface of the connector and also on a mating face on the bone bolt. In another embodiment, the spinal fixation system includes a dynamic, or movable, rod connector and a fixed rod connector which allows variation of the distances between vertebrae for compression or distraction.

One object of the invention is to provide an apparatus for use in laterally connecting longitudinal members implanted adjacent a patient's vertebral column.

Another object of this invention is to provide an apparatus which provides for convenient management of thoracolumbar burst fractures and tumors and which permits anterior load sharing as well as compression and distraction.

One benefit of the apparatus of the present invention is that it combines means for connecting the vertebral fixation elements to the spinal rods with means for laterally or transversely connecting the spinal rods together. An additional benefit is that the invention provides a more compact construct with a lower profile as compared to prior spinal rod constructs employing many individual components to connect vertebrae and spinal rods.

Yet another benefit achieved by the invention resides in providing segmental coupling or connection of the spinal rods, while permitting a wide variation of orientations at the vertebral fixation elements relative to the spinal rods.

Another advantage of this invention is that it provides fixation assemblies that can be top loaded, or implanted over bolts after the bolts have been engaged in the vertebrae.

Other objects and further benefits of the present invention will become apparent to persons of ordinary skill in the art from the following written description and accompanying figures.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an exploded perspective view of the spinal fixation system of the present invention including a pair of transverse connectors spanning between two spinal rods with a pair of vertebral fixation bolts and corresponding nuts.

FIG. 2 is an end elevational view of a transverse connector according to one embodiment.

FIG. 3 is a side cross-sectional view of a transverse connector engaged to a vertebra.

FIG. 4 is a side elevational view of a bone bolt according to one embodiment of the invention for use with the fixation system shown in FIG. 1.

FIG. 5 is a bottom elevational view of the lower surface of a transverse connector shown in FIG. 1.

FIG. 6 is a top elevational view of the bone bolt according to one embodiment as shown in FIG. 2.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to

the embodiments illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended, such alterations and further modifications in the illustrated devices, and such further applications of the principles of the invention as illustrated therein being contemplated as would normally occur to one skilled in the art to which the invention relates.

The present invention is useful for anterior internal fixation of the spine which is indicated for thoracolumbar burst fractures with significant canal compromise, vertebral body tumors, lesions due to infection, spondylolisthesis, degenerative discs, and post-laminectomy instability.

This invention provides a top-loaded, low profile anterior fixation system which requires minimal instrumentation yet permits anterior load sharing and compression or distraction. The unique constructs of this invention permit fixation and compression or distraction with only two bolts, two rods and two rod connectors.

A spinal fixation system **10** in accordance with a preferred embodiment of the present invention is depicted in FIG. 1. The system **10** includes a transverse connector **15** defining a thru-hole **16** and having a lower bone engagement surface **20** and an upper surface **23**. The transverse connector **15** engages a number of longitudinal members **11** by clamping surface **22** provided in a slot **21** defined in the connector **15**. Preferably the longitudinal members **11** are spinal fixation rods. In one embodiment, the members **11** are smooth shot peened rods.

Referring to FIGS. 1, 2, and 3, a number of fixation spikes **17** are fixedly attached to the lower surface **20** of the connector **15**. The lower surface **20** of the connector **15** in combination with an inner surface **19** of the fixation spikes **17** are configured to fit snugly around either side of a vertebra. In another application, the fixation spikes **17** may be slightly embedded into the vertebra. The end of each spike **17** is preferably beveled on its outer surface **24** so that each fixation spike **17** terminates in a wedge shape **18** which may aid in fixing and holding the connector **15** in place over a vertebra.

Bolts **30** are used to attach the system **10** to the vertebrae. It is understood that "bolt" refers to any of various bone fasteners, including a standard bone screw. The present invention is unique because it requires only one bolt per connector. Previous devices have required two. FIG. 4 shows one embodiment of a bolt **30** in detail. The bolt **30** has a vertebra engaging portion **31** at a first end **33** and a post **32** at a second end **35**. The vertebra engaging portion **31** of the bolt **30** may be configured, for example, with cancellous threads for fixation in the spongy bone of the vertebral body. The bolt also includes an integral flange **36** for supporting and clamping the connector **15**. In one embodiment, the second end **35** is configured to receive a driving tool. The configuration may include an internal or external hex as is well known in the art.

The fixation system **10** can be top-loaded, i.e., implanted over a bolt **30** after the bolt **30** is engaged to a vertebra. This is advantageous because it reduces the required size of the surgical opening and trauma to the patient. Top-loading also provides a mechanical advantage during implantation of the system. After a bolt **30** is engaged to a vertebra by conventional means, the post **32** is insertable through the thru-hole **16** of the connector **15**. A fastener **40** is provided for each of the bolts **30**. The fastener **40** engages to the post **32** of the bolt **30** to secure the connector **15** to the bolt **30** and to clamp the longitudinal members **11** within the slot **21** of the

connector **15**. Thus, the longitudinal members **11** and the connector **15** are secured by a single bolt **30**. Where the fastener **40** is a threaded nut, as in the preferred embodiment, the post **32** of the bolt **30** may include machine threads to engage with the nut. The nut or other fastener **40** is then top-tightened with a tool such as a socket wrench.

The connector **15** may define recesses **41** surrounding each thru-hole **16** defined in the connector **15**. Each recess can be configured to accept a fastener **40** in low profile so that the fastener **40** does not extend over the upper surface **23** of the connector **15** when it is engaged to a post **32**. The recesses **41** can be concave to accept an arcuate underside of the fastener **40**.

The spinal fixation system **10** may also be provided with a locking mechanism configured to prevent the bolts **30** from rotating relative to the connector **15** and the vertebra when the fastener or nut **40** is being tightened onto the bolt **30**. The locking mechanism also prevents the bolts from pulling out over time. In one embodiment of the invention, the locking mechanism includes an annular ring **45** defined on the lower surface **20** (FIG. 5) of the connector **15** and a mating face **50** affixed to each bolt **30** at a location between the post **32** and the vertebrae engaging portion **31**. The annular ring **45** on the lower surface **20** of the connector **15** is concentrically disposed around the thru-hole **16** and includes a number of radial splines **46**. Referring to FIGS. 1 and 6, the mating face **50** is concentrically disposed around and affixed to the bolt **30** and includes a number of opposing radial splines **51** for interdigitated engagement with the radial splines **46** on the lower surface **20** of the connector **15**. The annular ring **45** may alternately be a washer affixed to or a ring integrally formed on the lower surface **20** of the connector **15**.

The clamping surface **22** provided by the slot **21** defined in the connector **15** may include a number of scallops (FIG. 6). The scallops are configured to receive the longitudinal members **11** in a manner that is well known in the art. For example, each scallop can be generally formed at a radius that is slightly smaller than the radius of the longitudinal member **11** which is to be situated within the scallop. The scallops provide means for fixing the spinal rods so that the longitudinal members **11** and connector **15** do not shift relative to each other. However, it is understood that the slot **21** defined in the connector **15** may be smooth and that other means may be provided to firmly fix the longitudinal members **11**.

For example, in one embodiment, the slot **21** is smooth and the engagement of the longitudinal members **11** with the connector **15** is secured by a clamping action. The tightening of a fastener **40** on the post **32** causes a narrowing of the slot **21** of the connector **15** which in turn causes the connector **15** to securely clamp the longitudinal members **11**.

Another aspect of this invention provides means to vary the distance between vertebral bodies. According to the invention, a dynamic transverse connector **55** (FIG. 1) is slidable along the two longitudinal members **11** for compression and distraction of the vertebral bodies attached to the system **10**. One or more of other connectors **15** may be engaged to the longitudinal members at a fixed location. After compression or distraction is achieved, the dynamic connector **55** can be fixed by tightening the bolt **30** to which the connector **55** is fastened. The nuts **40** which attach to the bolts **30** can then be top tightened with a tool such as a socket wrench.

The invention also provides methods for fixating the spine which include drilling a first hole in a first vertebral body and drilling a second hole in a second vertebral body. A bone

bolt **30** is engaged to each of the first and second holes. The vertebrae are then supported with a fixation system **10** which includes two longitudinal members **11**, such as rods. A first connector **15** is attached to a first end of each of the longitudinal members **11**, and a dynamic rod connector **55** is slidably engaged to the longitudinal members **11**. One of the bone bolts **30** is engaged to the thru-hole **16** of the first connector **15**. The dynamic rod connector **55** is situated so that another bolt **30** engages a thru-hole **16** in the dynamic rod connector **55**. The dynamic rod connector **55** is then slid along the longitudinal members **11** to vary the distance between the first and second vertebrae. The post **32** of each bone bolt **30** is then engaged with a nut **40** to secure the fixation system **10** to the vertebrae. The dynamic rod connector **55** may be slid along the longitudinal members **11** in the direction towards the fixed connector **15** to compress the vertebrae before engaging the bone bolts **30** with the nuts **40**. The dynamic connector **55** may also be slid in a direction away from the fixed connector for distraction.

The spinal fixation system **10** is preferably formed of medical grade stainless steel or similar high strength material. Other materials are contemplated, provided the material is strong enough to endure the high loads transmitted through the components, and yet are biocompatible. Specifically, the system could be manufactured in 6A14V titanium or 316LVM stainless steel. The system can be provided in several different sizes ranging from, but not limited to, 2.0 inches to 5.5 inches.

While the invention has been illustrated and described in detail and the drawings and foregoing description, the same is to be considered as illustrative and not restrictive in character, it being understood that only the preferred embodiments have been shown and described and that all changes and modifications that come within the spirit of the invention are desired to be protected.

What is claimed is:

1. A spinal fixation system comprising:

at least two longitudinal members;

a one-piece transverse connector defining a thru-hole and having

a lower bone engagement surface,

an opposite upper surface, and

said connector defining a continuous slot intersecting

said thru-hole to receive said members and a number

of internal clamping surfaces surrounding said slot,

said clamping surfaces configured to engage said

members;

a bolt having

a vertebra engaging portion on a first end,

a post on an opposite second end, said post insertable through said thru-hole of said connector,

an integral flange between said vertebra engaging portion and said post for supporting said connector;

fixation means for provisionally holding said connector in engagement with a first vertebra;

a fastener engageable to the post of said bolt to secure the connector to the bolt and to clamp said connector between said fastener and said flange of said bolt; and

second means engageable to a second vertebrae and fixable to said longitudinal members for varying the distance between the first vertebra and a second vertebra for compression or distraction of the spine.

2. The system of claim 1 wherein the post of said bolt is threaded and the fastener is a threaded nut.

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3. The system of claim 2 further comprising a locking mechanism configured to prevent the bolt from rotating relative to said connector and the vertebra when the threaded nut is being threaded onto said post.

4. The system of claim 3 wherein said locking mechanism includes:

an annular ring defined on the lower surface of said connector and concentrically disposed around the thru-hole, said annular ring defining a number of radial splines; and

a mating face affixed to said flange and concentrically disposed around said post of said bolt, said mating face defining a number of opposing radial splines for interdigitating engagement with the radial splines on said lower surface of said connector.

5. The system of claim 4 wherein the annular ring is integrally formed on the lower surface of said connector.

6. The system of claim 4 wherein the annular ring is a washer affixed to the lower surface of said connector.

7. The system of claim 1 wherein the second end of said bolt is configured to receive a driving tool for driving the bolt into a vertebra.

8. The system of claim 7 wherein the second end includes an external hex configured to receive a driving tool.

9. The system of claim 7 wherein the second end includes an internal hex configured to receive a driving tool.

10. The system of claim 1 wherein said thru-hole includes a recess defined in the upper surface of said connector and said fastener is sized to be received in a recess without extending above the upper surface.

11. The system of claim 10 wherein said recess is concave and said fastener includes an arcuate underside, said recess configured to accept said fastener.

12. The system of claim 1 wherein the clamping surfaces are defined by a number of scallops formed in said slot, said scallops shaped to receive and engage said members therein, said scallops surrounding and clamping a portion of said members after the nut has been tightened on the post of the bolt.

13. The system of claim 1 wherein said fixation means includes a number of spikes projecting from said lower surface of said connector, said spikes configured to engage a vertebra.

14. The system of claim 1 wherein said second means includes a dynamic rod connector engageable to a second vertebra in the spine and having a lower surface and an upper surface and defining a thru-hole, said dynamic rod connector slidably engaged to each of said rods and moveable relative to said fixed rod connector to vary the distance between the first and second vertebrae.

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15. A spinal fixation system comprising:

two substantially parallel rods, each having a first end and a second end;

a fixed rod connector engageable to a first vertebra in the spine and having a lower surface and an upper surface and defining a thru-hole, said fixed rod connector immovably fixed to the first end of both of said rods;

a one-piece dynamic rod connector engageable to a second vertebra in the spine and having a lower surface and an upper surface and defining a thru-hole, said dynamic rod connector slidably engaged to each of said rods and moveable relative to said fixed rod connector to vary the distance between the first and second vertebrae, said dynamic rod connector fixable to said rods to fix the distance between the vertebrae;

one bolt for each connector, each said bolt having a vertebra engaging portion on a first end and a threaded post on an opposite second end, said post insertable through said thru-holes of said connectors;

each said bolt including an integral flange between said vertebra engaging portion and said post for supporting a corresponding connector; and

a threaded nut for each of said bolts, one nut engageable to one bolt to secure said fixed rod connector to said one bolt and the other nut engageable to the other bolt to compress said dynamic rod connector about said rods and to secure said dynamic rod connector to said other bolt.

16. The system of claim 15 wherein the second end of said bolt is configured to receive a driving tool for driving the bolt into a vertebra.

17. The system of claims 15 wherein the second end includes an external hex configured to receive a driving tool.

18. The system of claim 15 wherein the second end includes an internal hex configured to receive a driving tool.

19. The system of claim 15 wherein each said thru-hole includes recesses defined in the upper surface of said connector and said nut is sized to be received in a recess without extending above the upper surface.

20. The system of claim 19 wherein said recess is concave and said nut includes an arcuate underside, said recess configured to accept said nut.

21. The system of claim 15 wherein said dynamic rod connector defines a continuous slot to receive said rods and said slot includes internal clamping surfaces for engaging said rods, the clamping surfaces defined by at least two of scallops formed in said slot, said scallops shaped to receive and engage said rods therein, said scallops surrounding and clamping a portion of said rods after the nut has been tightened on the post of the bolt.

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